(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 856 300 A1

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
05.08.1998 Bulletin 1998/32

(51) Int. Cl.[6]: **A61F 2/24**, A61F 2/06

(21) Application number: **97310268.4**

(22) Date of filing: **18.12.1997**

(84) Designated Contracting States:
AT BE CH DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE
Designated Extension States:
AL LT LV MK RO SI

(30) Priority: **18.12.1996 NL 1004827**

(71) Applicant: **VenPro Corporation**
Irvine, California 92618 (US)

(72) Inventors:
- **Moll, Frans L.**
  3735 LA Bosch en Duin (NL)
- **Kalmann, Menno**
  8075 PD Elsp-eet (NL)

(74) Representative:
Harding, Charles Thomas et al
D. Young & Co.
21 New Fetter Lane
London EC4A 1DA (GB)

(54) Device for regulating the flow of blood through the blood system

(57) The invention relates to a device for regulating the flow of blood in blood vessels, comprising one or more flow stoppage elements, each comprising:

- a flareable proximal end, flareable between a flared, flow stoppage configuration and a substantially flattened, flow permitting configuration, and
- a middle section extending from the proximal end to terminate in a distal end, forming flexible, hollow cones.

Blood flowing back down the blood vessel between heartbeats is caught in the three temporary blood storage areas so formed, and is forced back out as blood is pumped through the system by the heart.

EP 0 856 300 A1

Printed by Xerox (UK) Business Services

Description

The present invention relates to a device for regulating the flow of blood in blood vessels.

The blood system, and in particular the venal blood system of the legs and arms are provided with valves, at predetermined positions, which ensure that blood cannot flow back along the system in the direction from which it has just been pumped, to only be displaced in the direction of the heart.

In the arms and legs, there is a deep and a surface venal system.

Due to various causes, thrombosis can occur in especially the deep venal system. Following thinning of the blood, passage of the blood through the system is often again possible, but in this case the valves do not effectively close off the system and often leak. This causes an increased venal blood pressure in the direction of the ankles, which leads to many problems, such as varicose veins and the infamous "open leg". This type of complaint, is wide spread among people who spend a vast majority of their working hours in a standing position, for instance surgeons.

The surface venal system of the leg is weaker than the deep system, and has the tendency to spontaneously widen, whereby the valves no longer function effectively, leading to varicose veins, which, apart from being highly unattractive, are also very painful. Major surgery is often required to deal with these blood vessel valve problems.

For example varicose veins are presently surgically operated on, by either closing off the vein, which leads to a reduced blood flow capacity and extra pressure on surrounding blood vessels in order to ensure blood supply, or by completely removing the varicose veins, which leads to the same problem.

An object of the present invention is to obviate one or more of these problems.

According to a first aspect, the present invention provides a device for regulating the flow of blood in blood vessels, comprising one or more flow stoppage elements, each comprising:

- a flareable proximal end, flareable between a flared, flow stoppage configuration and a substantially flattened, flow permitting configuration, and
- a middle section extending from the proximal end to terminate in a distal end.

By introducing a synthetic device which acts as a valve, the blood flow is now able to be regulated in substantially the normal manner.

The device preferably further comprises:

- an opening associated with the proximal end, the middle section comprising one or more sidewalls extending from this proximal end opening to join together at the distal end, the sidewalls being displaceable, by the flow of blood through the device between the flared configuration, wherein the element encloses a temporary blood storage area, and the substantially flattened configuration wherein the one or more sidewalls lie substantially flat adjacent to each other.

When occupying the blood flow stoppage configuration, the flow stoppage element encloses a temporary blood storage area between its open proximal end and the closed distal end. In this way between heartbeats, which force the blood through the venal system, any blood flowing in the opposite direction to the blood stream opens the proximal end of the stoppage element thereby forcing the sidewalls apart to enter the temporary blood storage area, instead of passing through the device to leak back into the blood vessel in the direction from where it has just been pumped. Since opening of the blood flow stoppage element effectively closes off the blood vessel, a very effective valve is provided.

The flow stoppage element is preferably mounted on a support having such a form as to pass within a blood vessel. This provides extra stability.

The stoppage element is preferably substantially conical in shape when occupying the blood flow stoppage configuration, the closed distal end being synonymous with the tip of the cone and the proximal end opening being synonymous with the flared base of the cone. This yields a highly effective valve working.

The support is preferably adjustable between an introducing form, wherein the device is suitable for introducing into a blood vessel, and an expanded form suitable for supporting the stoppage element within a blood vessel at the desired working location thereof, and most preferably has such a form as to have substantially the same length when occupying its introducing form as when occupying its expanded form. Accordingly the device can be effectively introduced to a pre-desired location within a blood vessel, whereafter it is expandable to take up its working form. Since the support has substantially the same length when in its introducing form as in its expanded form, the stoppage elements remain effectively supported, and any damage ensuing from alteration of the length of the support within the blood system is effectively obviated.

In order to yield a very effective valve working, the support preferably comprises substantially separate frame sections for each of the one or more fluid passage stoppage elements.

According to another aspect of the present invention, there is provided a support for a fluid stoppage element as referred to above.

According to yet a further aspect of the present invention there is provided a method for regulating the flow of blood in the blood stream comprising introducing the above device into a blood vessel, so that the distal end thereof is arranged downstream from the proximal end, wherein the proximal end opening is closed by the

pressure of blood flowing through the device, as blood is pumped through the system by the heart, wherein blood flowing in the opposite direction to which it is pumped between beats, flows into the proximal end of the device, which is subsequently thereby opened to force the sidewalls of the device against the blood vessel walls, thereby closing off the passage of blood in the blood vessel, wherein blood is trapped in the temporary blood storage area enclosed by the sidewalls of the device before a subsequent volume of blood being pumped through the device claps said sidewalls shut, thereby expelling blood out of the temporary storage area and further through the system.

The present invention will now be further clarified by way of the following specific description, which refers to figures 1 to 7, wherein:

figure 1 is a perspective view of the device according to the present invention;
figure 2 is a side view of a support for a flow stoppage element according to the present invention,
figure 3 is a perspective view of the device from figure 1, when occupying its introducing form, as to be introducible into a blood vessel;
figure 4 is a perspective view showing the introduction of a device as shown in figure 1 into a blood vessel;
figure 5 is a perspective view as in figure 4, showing the device when occupying its blood flow through put position;
figure 6 shows the device from figure 1, with the support (not shown) in order to provide maximum clarity, when occupying its blood flow stoppage position within a blood vessel; and
figure 7 is a perspective view of two devices as shown in figure 1, when placed in a vein in the leg.

A device 1 (figure 1) according to the present invention has a proximal end 2 and a distal end 4.

Blood flow stoppage elements 6, having the form of flexible hollow cones, are each supported on a substantially triangular frame section 8 of a support 10, see also figure 2.

The valve elements 6 have an inner wall 12 and an outer wall 14 extending from a proximal end (2) opening 16 in the "flared" configuration to join together and terminate in the form of a pointed end section 18 at the distal end 14.

The support 10 is preferably made of a continuous length of memory metal, having, as shown in figure 1 and 2, three substantially separate frame sections 8 for supporting each valve element 6.

As shown in figure 3, the frame 10 can be rolled up so that frame sections 8 partially overlap one another.

In such a position the device 1 is easily introduced into a blood vessel.

On being placed at its desired position within the blood system, the device, once the memory metal has achieved a particular predetermined temperature, will expand in order to assume its working form as shown in figure 1, whereby since in its introducing form (figure 3), an area of overlap exists between the terminal frame sections 8, the device 1 remains substantially the same length in its working position (figure 1) as in it introducing position (figure 3).

In order to ensure biocompatibility, the support and blood stoppage elements are made of biocompatible material, whereby the blood stoppage elements are most preferably made of polytetrafluoroethylene (PTFE).

The device 1 is folded up into its introducing form, as shown in figure 3, whereafter once arranged in an introducing device 18, as shown in figures 3 and 4, the device 1 is introducible into a blood vessel 20 as shown in figure 4.

On assuming its working configuration as shown in figures 1, 5, 6 and 7, the blood is regulated in the blood vessel by the device as follows.

Blood is pumped through the blood Vessel 20 (figure 5) and through the device 1 (figure 5) on the beat of the heart. This means that instead of flowing at a constant rate through the blood vessel, that blood flows through the blood system, in particular through veins, as a series of pulses. Between each pulse, the blood is not being actively forced through the system and can flow back from where it came.

When actively pumped through the system, blood is forced through the device 1 through the distal end 4 and out of the proximal end 2 (figure 5).

In this position (figure 5), the flow of the blood through the device 1, forces the inner walls 12 of the stoppage elements 6 against the outer walls 14 thereof in order to effect a blood flow through channel.

Between heartbeats, blood having just passed through the proximal opening 2 of the device 1, can flow back down the blood vessel 20. On doing so, it forces the inner walls 12 away from the outer walls 14 of these elements 6 at the proximal end 2 of the device 1 to create the opening 16 leading into a temporary blood storage area 22. Since the inner walls 12 and the outer walls 14 are joined together at the distal end 4 of the device, the temporary blood storage area 22 is effected in each blood stoppage element 6 at this phase (figure 6).

During the next pulse of blood through the device 1 from the distal end 4, the inner walls 12 are forced against the outer walls 14 of the stoppage elements 6, thus forcing the blood temporarily stored therein out of the blood stoppage elements 6 and effecting the open channel to enable blood through flow.

Claims

1. Device for regulating the flow of blood in blood vessels, comprising one or more flow stoppage elements, each comprising:

- a flareable proximal end, flareable between a flared, flow stoppage configuration and a substantially flattened, flow permitting configuration, and
- a middle section extending from the proximal end to terminate in a distal end.

2. Device according to claim 1 further comprising:

   - an opening associated with the proximal end, the middle section comprising one or more sidewalls extending from this proximal end opening to join together at the distal end, the sidewalls being displaceable, by the flow of blood through the device between the flared configuration, wherein the element encloses a temporary blood storage area, and the substantially flattened configuration wherein the one or more sidewalls lie substantially flat adjacent to each other.

3. Device according to claims 1 or 2, wherein the flow stoppage element is mounted on a support having such a form as to pass within a blood vessel.

4. Device according to claims 1, 2 or 3, wherein the flow stoppage element is substantially conical in shape, when occupying the flared configuration, the distal end being synonymous with the tip of a cone and the proximal end opening being synonymous with the base of a cone.

5. Device according to claims 3 or 4, wherein the support is adjustable between an introducing form, wherein the device is suitable for introducing into a blood vessel, and an expanded form suitable for supporting the flow stoppage element within a blood vessel at the desired working location thereof.

6. Device according to claim 5, wherein the support has such a form as to have substantially the same length when occupying its introducing form as when occupying its expanded form.

7. Device according to claim 6, wherein the support comprises separate frame sections for each of the one or more flow stoppage elements.

8. Device according to claim 7, wherein the support contacts the distal end, the one or more sidewalls and at least one side of the opening associated with the proximal end of each fluid passage stoppage element.

9. Device according to claim 8, wherein the substantially separate frame sections of the support are overlappable when the device occupies its introducing form.

10. Device according to any of the claims 3-9, wherein the support is made of memory metal, preprogrammed to expand from its introducing form into its expanded form at a predetermined temperature within a blood vessel.

11. Device according to any of the previous claims, wherein the support and the flow stoppage element are made of biocompatible material.

12. Support as described in any of the claims 3-11, for supporting a flow stoppage element as described in any of the preceding claims.

13. Method for regulating the flow of blood in the blood stream comprising introducing a device according to any of the claims 1-11, into a blood vessel, so that the distal end thereof is arranged downstream from the proximal end, wherein the proximal end opening is closed by the pressure of blood flowing through the device, as blood is pumped through the blood system by the heart, wherein blood flowing in the opposite direction to which it is pumped between beats, flows into the proximal end of the device, which is subsequently thereby opened to flare the sidewalls of the device against the blood vessel walls, thereby closing off the passage of blood in the blood vessel, wherein blood is trapped in the temporary blood storage area enclosed by the sidewalls of the device before a subsequent volume of blood being pumped through the device claps said sidewalls shut, thereby expelling blood out of the temporary storage area and further through the system.

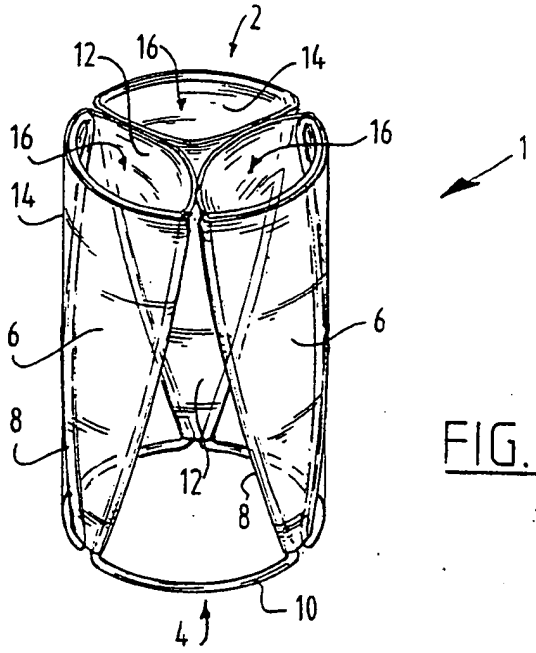

FIG.1

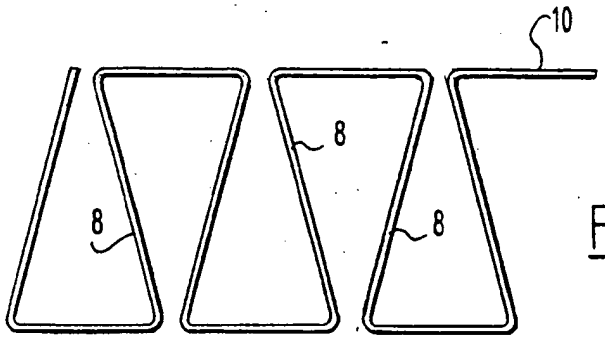

FIG.2

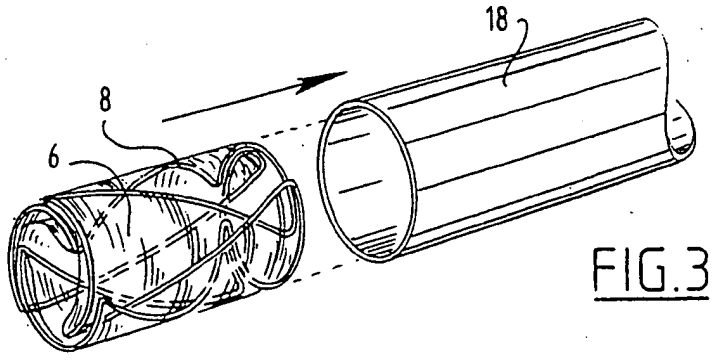

FIG.3

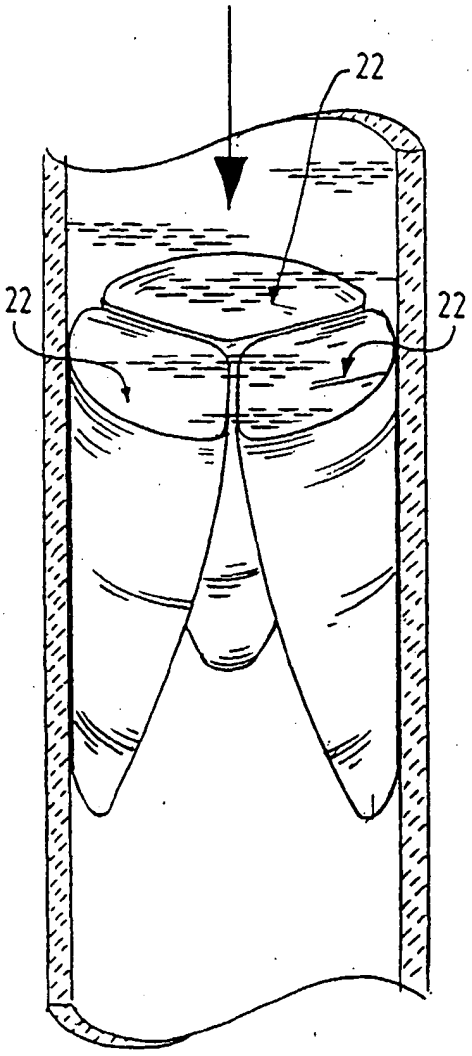

FIG.6

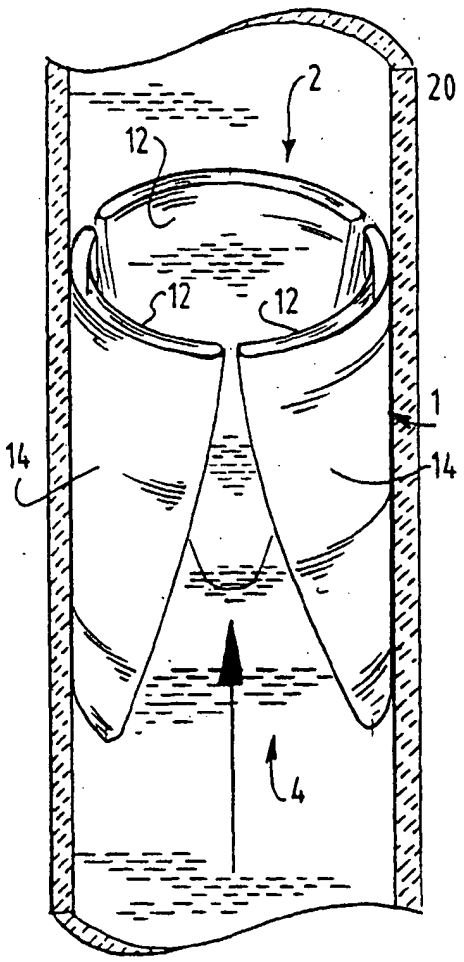

FIG.5

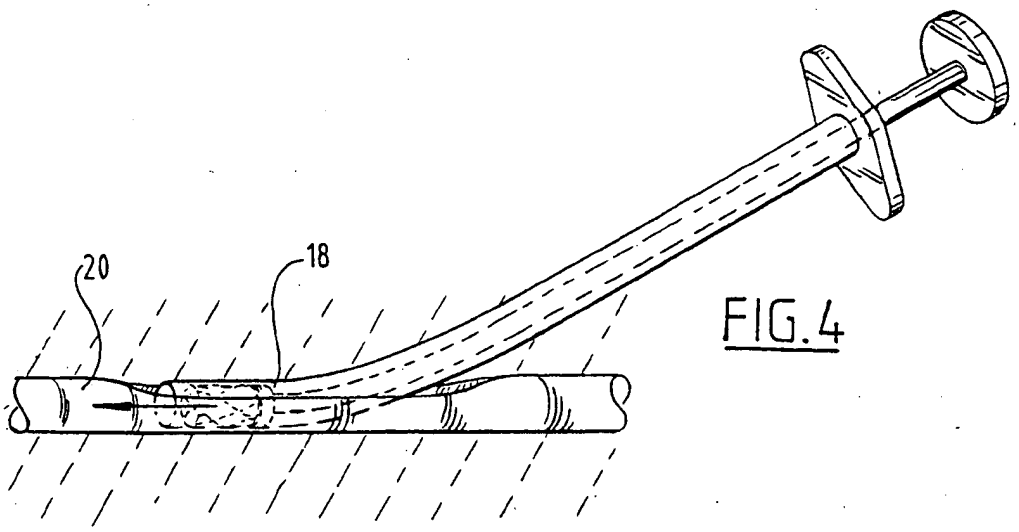

FIG.4

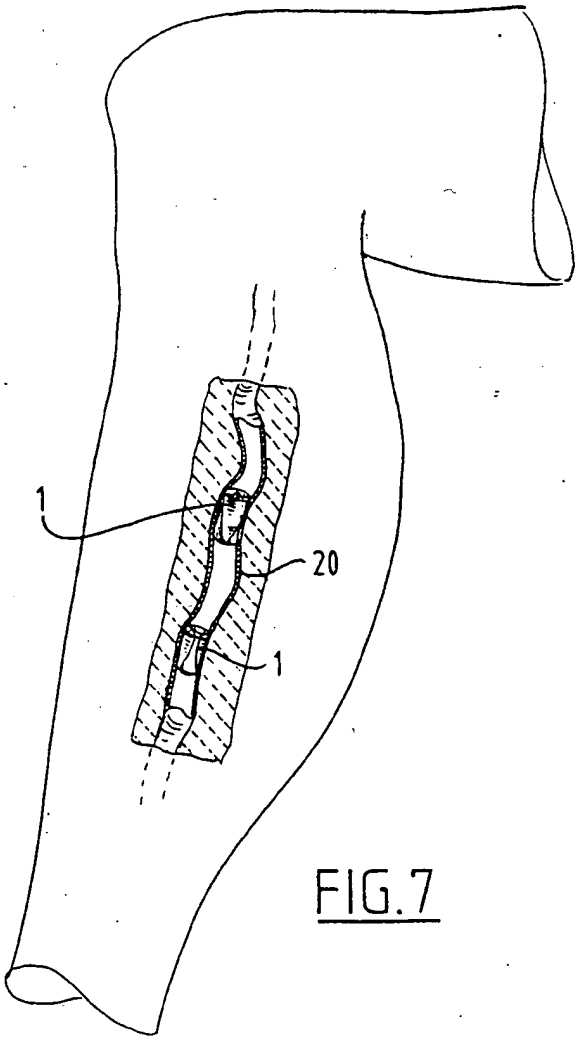

FIG.7

European Patent Office

PARTIAL EUROPEAN SEARCH REPORT

which under Rule 45 of the European Patent Convention shall be considered, for the purposes of subsequent proceedings, as the European search report

Application Number EP 97 31 0268

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
P,X	DE 195 32 846 A (BERG) 13 March 1997 * the whole document * ---	1-8, 10-12	A61F2/24 A61F2/06
X	WO 96 19159 A (FRANCESCHI ET AL) 27 June 1996 * abstract; figures * ---	1,2,4	
X	GB 1 477 643 A (NATIONAL RESEARCH DEVELOPMENT) 22 June 1977 * the whole document * ---	1,2	
A	DE 19 32 817 A (CAMILLI) 2 January 1970 * abstract; figures * ---	3	
A	EP 0 667 133 A (BELLHOUSE ET AL) 16 August 1995 -----		

TECHNICAL FIELDS SEARCHED (Int.Cl.6)

A61F

INCOMPLETE SEARCH

The Search Division considers that the present application, or some or all of its claims, does/do not comply with the EPC to such an extent that a meaningful search into the state of the art cannot be carried out, or can only be carried out partially, for the following claims:

Claims searched completely :

1-12

Claims searched incompletely :

Claims not searched :

13

Reason for the limitation of the search:

Article 52 (4) EPC - Method for treatment of the human or animal body by surgery

Place of search	Date of completion of the search	Examiner
THE HAGUE	9 April 1998	Hagberg, A

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P04C07)